NC DEPARTMENT OF HEALTH AND HUMAN SERVICES

NC State Health Director's Statewide Standing Order
Moderna COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5) Vaccine Administration for Children 6 months through 5 years
April 21, 2023

Purpose: To reduce morbidity and mortality from coronavirus disease 2019 (COVID-19) by vaccinating persons who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP) and to administer Moderna COVID-19 vaccine to persons who meet criteria set-forth by the Food and Drug Administration in accordance with FDA Emergency Use Authorization.

Policy: This standing order authorizes any North Carolina healthcare provider, in accordance with the conditions of their licensure, or pursuant to orders issued under North Carolina Session Law 2022-74, Sec. 9G.7.(a)-(e) or as a covered person under the federal PREP Act functioning as vaccinating providers (collectively "vaccinators") to administer COVID-19 Vaccines authorized by the FDA per conditions of this order.

NOTE: On December 8, 2022, the FDA authorized the use of a **new** Moderna COVID-19 bivalent booster for children ages 6 months through 5 years. This **new** product will be referred to as **"Moderna COVID-19 Vaccine, Bivalent"** throughout the entirety of this standing order.

NOTICE: On January 26, 2023, the FDA revised the EUA for EVUSHELD and rescinded authorization for use in the United States until further notice by the agency. EVUSHELD is no longer effective against the most prevalent circulating strains of SARS CoV2. Therefore, any recommendations for use as a therapeutic for COVID-19 have been removed from this standing order.

Note: On April 18, 2023, the FDA rescinded the EUA of all mRNA **monovalent** COVID-19 vaccine products. This decision was based on data reflecting the overall improved effectiveness of the bivalent vaccines vs. monovalent vaccines and the fact that the most prominently circulating SARS- CoV2 strains are of Omicron BA.4/BA.5 lineage. This action also simplifies the vaccination schedule for most individuals.

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COVID-19 Vaccination	
Condition/Situation:	Patients who present requesting a vaccination will receive, with appropriate written consent from an authorized caregiver: **Individuals 6 months through 5 years of age:** • **Unvaccinated individuals**: Administer two doses of Moderna COVID-19 Vaccine, Bivalent. The second dose shall be administered 1 month after the first. • **Individuals who have received one dose of Moderna COVID-19 Vaccine**: Administer a single dose of Moderna COVID-19 Vaccine, Bivalent 1 month after the dose of Moderna COVID-19 Vaccine. • **Individuals who have received two doses of Moderna COVID-19 Vaccine**: Administer a single dose of Moderna COVID-19 Vaccine, Bivalent at least 2 months after the last dose of Moderna COVID-19 Vaccine. • **Immunocompromised individuals 6 months through 5 years of age:** For children who have received two doses (Moderna COVID-19 Vaccine or Moderna COVID-19 Vaccine, Bivalent), administer a single additional dose of Moderna COVID-19 Vaccine, Bivalent at least 1 month following the most recent dose of Moderna COVID-19 Vaccine, Bivalent. o If the parent requests an additional doses of Moderna COVID-19 Vaccine, Bivalent for their immunocompromised child, refer to their healthcare provider for an individual medical order. Mixing different manufacturer vaccine products is not authorized in this age group. To determine previous vaccination status consult NCIR/CVMS, child's vaccination card, or accept parental attestation. **For individuals with certain kinds of immunocompromise 6 months through 5 years of age** who have received two 0.25 mL doses (Moderna COVID-19 Vaccine or Moderna COVID-19 Vaccine, Bivalent), an additional 0.25 mL dose of Moderna COVID-19 Vaccine, Bivalent (vial with a dark blue cap and a label with a gray border) shall be administered at least 1 month following the most recent dose: additional doses of Moderna COVID-19 Vaccine, Bivalent may be administered at the discretion of the healthcare provider, taking into consideration the individual's clinical circumstances.
Condition	In addition to criteria above, the following conditions regarding consent must be met: • Patients (recipients of vaccine) 6 months through 5 years of age presenting for vaccination whose parent or legal guardian has provided **written** consent to the vaccine will be vaccinated under FDA-Emergency Use Authorization (EUA) status**.**
Assessment Criteria	

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Assessment Criteria	Patients shall be vaccinated with Moderna COVID-19 Vaccine, Bivalent 6 mos.-5 years based on: 1. The conditions/situations of this order (see above).
Plan of Care	
Actions	**Patient Education and Data Collection** Prior to patients receiving the COVID-19 booster vaccine, the vaccinator or designee (if delegation permitted by licensure and/or law) shall provide anticipatory guidance regarding vaccination to the patient, which at a minimum shall include: 1. Review CDC Pre-Vaccination Checklist for COVID-19 Vaccine 2. Fact Sheet for Recipients and Caregivers for Moderna COVID-19 Pediatric Bivalent vaccine 6 months through 5-years 3. Patient's authorized caregiver should consult primary care or other health care provider if they have questions regarding which COVID-19 vaccine they should receive for primary and booster doses. Refer to Interim Clinical Considerations for latest vaccine information.
	Moderna COVID-19 Vaccine, Bivalent, 6 months through 5-years **Administration Procedures:** 1. Review Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States. 2. Review the fact sheet for healthcare providers: Moderna HCP Fact Sheet 6m-5y 12082022 (fda.gov) 3. Moderna COVID-19 Vaccine, Bivalent is supplied in two different formulations for this age group. Administer the formulation based on previous vaccine history, age and intervals in the charts below. **Individuals 6 Months of Age and Older <u>Not Previously Vaccinated</u> with Any COVID-19 Vaccine**

Age	Moderna COVID-19 Vaccine, Bivalent Vial Cap and Label Color	Dosing Regimen, Dose, and Schedule
6m-5y	Dark Blue Cap and a Label with Gray Border	2 doses, 0.25 mL each Dose 1: month 0 Dose 2: month 1

Individuals 6 Months Through 5 Years of Age Previously Vaccinated with Moderna COVID-19 Vaccine[3]

Age	Number of Previous Doses of Moderna COVID-19 Vaccine	Moderna COVID-19 Vaccine, Bivalent Vial Cap and Label Color	Dosing Regimen, Dose and Schedule
6m-5y	1 previous dose	Dark Blue Cap and a Label with Gray Border	Single Dose, 0.25 mL One month after receipt of Moderna COVID-19 Vaccine
6m-5y[4]	2 previous doses	Dark Pink Cap and a Label with a Yellow Box	Single dose, 0.2 mL ≥2 months after receipt of Moderna COVID-19 Vaccine

[3] The monovalent Moderna COVID-19 Vaccine is no longer authorized for use in the United States.
[4] For individuals with certain kinds of immunocompromise (as defined in footnote 6), see text below tables for dosing regimen, dose and schedule.

For individuals with certain kinds of immunocompromise **6 months through 5 years of age** who have received two 0.25 mL doses (Moderna COVID-19 Vaccine or Moderna COVID-19 Vaccine, Bivalent), an additional 0.25 mL dose of Moderna COVID-19 Vaccine, Bivalent (vial with a dark blue cap and a label with a gray border) may be administered at least 1 month following the most recent dose; additional doses of Moderna COVID-19 Vaccine, Bivalent may be administered at the discretion of the healthcare provider, taking into consideration the individual's clinical circumstances

4. Appropriate medical treatment and clinical staff able to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration.
5. A medical provider, defined as a physician, physician assistant, nurse practitioner, or a pharmacist authorized to order COVID-19 vaccines by the PREP Act must be accessible to provide medical supervision of the vaccination site/service, to assess and evaluate individuals who present with contraindications or precautions to vaccination, and to answer questions or address problems with carrying out this standing order. This may be telephone or virtual accessibility.

6. Review *Special Circumstances*, *Precautions*, *Contraindications*, *and Criteria or Circumstances for Notifying Medical Provider* sections of this standing order **before** administering the COVID-19 booster vaccine. For additional information see COVID-19 Vaccines for Special Populations.
7. Following the current *CDC Pre-Vaccination Checklist for COVID-19 Vaccines*, instruct patients accordingly or consult with overseeing provider.
    a. The pre-vaccination checklist shall be followed with the following exception: COVID-19 vaccination should ***not*** be deferred in patients who received monoclonal antibody treatment or convalescent plasma.
8. Individuals under 18 presenting for COVID vaccine must have written consent from the patient's authorized parent or caregiver prior to administration per agency policy and in accordance with NC General Statute. 90-21.13.
9. Personal Protective Equipment: Before administering the COVID-19 vaccination, don appropriate personal protective equipment (PPE) per CDC guidelines for COVID-19 vaccinations to protect against the transmission of COVID-19.

Vaccine Product & Preparation:

1. **Vaccine Preparation**: Follow manufacturer's guidance for storing/handling vaccine. This product **does not** require diluent. Discard **8 hours** after first puncture.
2. **Dosing:** See #3 under Administration Procedures

When a patient inadvertently receives an incorrect or inappropriate dose of any COVID-19 vaccine, review Interim Clinical Considerations, Appendix D for COVID-19 vaccine errors and deviations, and take action as directed.

3. **Timing:** See #3 Administration Procedures
4. **Administration:**

a. Route of Administration: Use the chart below to determine appropriate needle gauge and site of intramuscular injection.

Age of Patient	Needle Gauge	Needle Length	Injection Site
Infants, 6-12 months	25 mm	1 inch	Anterolateral thigh
Toddlers, 1-2 years	25-32 mm	1-1.25 inch	Anterolateral thigh
	16-25 mm	*5/8 inch-1 inch	Deltoid muscle
Children, 3-5 years	16-25 mm	*5/8 inch-1 inch	Deltoid muscle
	25-32 mm	1-1.25 inch	Anterolateral thigh

b. Needle Gauge: Changing needles between drawing up vaccine from a vial and injecting it into a patient is not necessary unless the needle has been damaged, contaminated, or if the needle used to draw up the vaccine is not the correct size for the patient based on their reported weight. Patient's authorized caregiver may self-report

	the child's weight for needle selection purposes. *If a 5/8-inch needle is used, skin must be stretched tightly (**do not bunch subcutaneous tissue**). 5. **Multiple vaccinations:** If multiple vaccines are administered at a single visit, administer each injection in a different injection site following guidance in the CDC Interim Clinical Considerations on Coadministration of COVID-19 vaccines with other vaccines. 6. **Bleeding Risk**: Patients with blood disorders or who are on blood thinners: administer the vaccine using a 23 gauge or smaller caliber needle, followed by firm pressure on the site, without rubbing, for at least 2 minutes. 7. **Documentation:** a. **NCIR**: Document vaccine record in CVMS or NCIR **within 24 hours** after vaccine administration per system guidelines found at: https://immunize.nc.gov/providers/covid-19training.htm. If vaccine is documented in the EHR within 24 hours, providers have **no more than 72 hours** from administration to also enter data in CVMS or NCIR. b. **Electronic Medical Record**: If necessary for billing or other purposes, document patient COVID-19 vaccination in agency electronic medical record per agency policy. c. Provide recipient's authorized caregiver COVID-19 Vaccination Record Card indicating the vaccine dose number, product name/manufacturer, lot number, date of vaccination, name/location of vaccinator and clinic site.
	Moderna COVID-19 Pediatric Bivalent vaccine 6 months through 5-years: Observation and Follow-Up **1. Post-vaccination Observation**: Nurses, EMS, or other individuals who are trained and supervised by clinical staff shall observe patients post-vaccination for immediate allergic reactions according to the Centers for Disease Control and Prevention guidelines for the following time periods: a. 30 minutes: i. Persons with a history of an immediate allergic reaction of any severity to a non-COVID-19 vaccine ii. Persons with a history of anaphylaxis due to any cause iii. People with a contraindication to a different type of COVID-19 vaccine (for example, people with a contraindication to a viral vector vaccine-Janssen/Johnson and Johnson who receive a mRNA vaccine-COMIRNATY/Pfizer or Moderna) should be observed for 30 minutes following vaccination. iv. Persons with an immediate (within 4 hours of exposure) non-severe allergic reaction to a COVID-19 vaccine or injectable therapy b. 15 minutes: All other persons

	2. **Anaphylaxis Management**: Be prepared to manage medical emergencies by following your emergency response policies, procedures, and standing orders for any vaccine reaction, which must include appropriate equipment and medications (e.g., epinephrine, diphenhydramine) where vaccines are provided to respond to severe allergic reactions and anaphylaxis. 3. **Syncope:** Be prepared to manage syncope as it may occur in association with administration of injectable vaccines, particularly in adolescents. Procedures should be in place to avoid injury from fainting.
Special Circumstances	**People who received COVID-19 vaccination outside the United States:** The recommendations for people vaccinated outside of the United States depend on the vaccine(s) received for the primary series, whether the primary series was completed, and whether a booster dose was received. Refer to Interim Clinical Considerations, Appendix A (People who received COVID-19 vaccine outside the United States) and take action/ consult with medical provider as directed. • **Participants in clinical trials within or outside the United States** who received all the recommended primary series doses of a WHO-EUL COVID-19 vaccine (i.e., not placebo) that is not FDA-approved or FDA-authorized are considered fully vaccinated. In addition, individuals who received a vaccine that is not listed for emergency use by WHO but for which a U.S. data and safety monitoring board or equivalent has independently confirmed efficacy are considered fully vaccinated. *These persons require medical consultation. • If clinical trial participants have questions about whether they should receive an additional and/or booster dose outside of the clinical trial, they should consult with their healthcare provider. Clinical trial participants who did not receive all the recommended doses, or who received other vaccines not listed above, should consult with their healthcare provider to determine if they should receive an FDA-approved or FDA-authorized COVID-19 vaccine series. For more information, refer to Interim Clinical Considerations, Appendix B (People who received COVID-19 vaccine as part of a clinical Trial)
Follow-up	Adverse events that occur in a recipient following COVID-19 vaccination should be reported to VAERS. Information on preventing, reporting, and managing COVID-19 vaccine administration errors is found in Appendix D. Vaccine administration errors and deviations. Vaccination providers are required by the FDA to report the following that occur after COVID-19 vaccination under BLA or EUA: • Vaccine administration errors • Serious adverse events • Cases of Multisystem Inflammatory Syndrome • Cases of COVID-19 that result in hospitalization or death

	Reporting is encouraged for any other clinically significant adverse event, even if it is uncertain whether the vaccine caused the event. Information on how to submit a report to VAERS is available at https://vaers.hhs.gov or by calling 1-800-822-7967.
Precautions for Use of this Order	1. Persons with a history of an immediate allergic reaction to any other vaccine other than COVID-19 vaccine or to any injectable therapy (i.e., intramuscular, intravenous, or subcutaneous vaccines or therapies [excluding subcutaneous immunotherapy for allergies, i.e., "allergy shots"]). This includes people with a history of an immediate allergic reaction to a vaccine or injectable therapy that contains multiple components, one of which is a COVID-19 vaccine component, even if it is unknown which component elicited the immediate allergic reaction. 2. Persons with a contraindication to one type of a COVID-19 vaccine (e.g., viral vector – Janssen/Johnson and Johnson) have a precaution to another (e.g., mRNA – COMIRNATY/Pfizer or Moderna) because of potential cross-reactive hypersensitivity. Consultation with an allergist-immunologist should be considered prior to vaccination and patients with this precaution should be vaccinated in a health care setting where allergic reactions can be immediately managed and under the supervision of a health care provider experienced in the management of severe allergic reactions. 3. Patient self-reported moderate to severe acute illness. 4. Persons with a precaution to vaccination must be counseled about the unknown risks of experiencing a severe allergic reaction and balance these risks against the benefits of vaccination. 5. Persons with a history of myocarditis or pericarditis. 6. Persons with a history of MIS-C or MIS-A.
Contraindications for Use of this Order	Do not administer the COVID-19 Vaccine to individuals with a history of: • Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of the vaccine • Immediate allergic reaction of any severity to a previous dose or known (diagnosed) allergy to a component of the vaccine. See Appendix E: Interim Clinical Considerations for Use of Covid-19 Vaccines Currently Approved or Authorized in the United States

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Criteria or Circumstances for Notifying Medical Provider	1. Allergic reaction: Call 911, implement medical emergency protocols and immediately notify the medical provider providing clinical supervision of the vaccination site/service. 2. Patient reports a precaution for the vaccine. 3. COVID-19 Vaccine history cannot be determined or is not available. 4. Patients vaccinated with COVID-19 vaccines not authorized or approved in the US. 5. Patients vaccinated with active COVID-19 vaccine as part of a clinical trial. 6. Patient reports they are a HCT or CAR-T cell recipient. These patients may need revaccination, dependent on when the transplant or therapy occurred. 7. Notify the Medical Provider from the organization providing clinical supervision of the vaccination site/service at any time there are questions or problems with carrying out this standing order. Note: Healthcare providers or health departments in the United States can request a consultation from CISA COVID for a complex COVID-19 vaccine safety question that is (1) about an individual patient residing in the United States or vaccine safety issue and (2) not readily addressed by CDC or Advisory Committee on Immunization Practices (ACIP) guidelines.

Approved by: _ CTilson ___ Date Signed: _4-21-23_____

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This standing order is effective immediately and authorizes any North Carolina healthcare provider, in accordance with the conditions of their licensure, or pursuant to orders issued under North Carolina Session Law 2022-74, Sec. 9G.7.(a)-(e) or as a covered person under the federal PREP Act functioning as vaccinating providers (collectively "vaccinators") to administer COVID-19 Vaccines authorized by the FDA per conditions of this order.